

## **Remarks/Arguments**

Applicant have previously cancelled Claims 3 - 28. With this response Applicants cancel claims 29, 30, 33, 36-37, 40, 43, 47, 51, 55 and 59. Claims remaining in this application are Claims 1, 2, 31, 32, 34, 35, 38, 39, 41, 42, 44 - 46, 48 - 50, 52 - 54, 56 - 58 and 60.

### **Rejections for double-patenting:**

The Examiner has made provisional obviousness-type double patenting rejections over copending applications 10/111,027, 10/111,028 and 10/111,029. Applicants believe that the amendments to the claims submitted herewith obviate the Examiner's rejections and respectfully request that the Examiner reconsider and withdraw the double-patenting rejections.

### **Rejections under 35 U.S.C. § 112:**

The Examiner has rejected Claims 1, 2 and 29-60 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states, "the claim language is drawn to a method of treatment using an agent which is not described structurally/formulaically/nomenclatorially but rather by the agent's mode of action, function or effect requisite to an activity produced by the composition."

The Examiner will appreciate that the simple absence of the particular distinct identity or agent is not sufficient to make a claim indefinite. Paragraph 6 of Section 112 of Title 35 of the United States Code states "an element in a claim for a combination may be expressed as a means of step for performing a specified function without the recital of structure . . . ." Paragraph 6 further states "such claim shall be construed to cover the corresponding structure material or act described in the specification and equivalents thereof." Applicants respectfully point out that the pharmaceutical composition claimed in Claim 1 is a combination of a positive modulator of a nicotinic receptor agonist and a pharmaceutically acceptable carrier.

Notwithstanding the foregoing, Applicants have amended Claims 1 and 34 to expressly recite that the positive modulator is 5-hydroxyindole.

As regards the nicotine receptor agonists recited in the claims, Applicants direct the Examiner's attention to the specification wherein guidance is provided to agonists suitable for use in the present invention. Particularly, the Examiner's attention is drawn to page 6, lines 20 through 24 which recites, "In another preferred form of the invention, the said nicotinic receptor agonist is an  $\alpha$ 7-nicotinic receptor agonist. Example of an  $\alpha$ 7-nicotinic receptor agonist is (-)-Spiro[1-Azabicyclo[2.2.2.]Octane-3,5\*-Oxazolidine]-2\*-One. Several  $\alpha$ 7-nicotinic receptor agonists are known in the art, e.g. from WO 96/06098, WO 97/30998 and WO 99/03859." As the Examiner will appreciate, there is nothing indefinite about the compounds described as being suitable nicotinic receptor agonists.

Therefore, in view of the foregoing, Applicant respectfully requests that the Examiner withdraw the rejection of the claims of the present application under 35 U.S.C. S 112(b) as being indefinite.

**Rejections under 35 U.S.C. § 102(b):**

The Examiner has rejected claims 1 and 29 under 35 U.S.C. § 102(b) as being anticipated by Grollier *et al.*, (US Patent 5,135,544 ("544")).

The Examiner states, "Grollier et al. disclose a composition comprising 5-hydroxyindole."

Applicants respectfully point out that '544 does not disclose each element of the present invention as claimed: Indeed, it does not disclose the present invention at all. Rather, U.S. patent '544 is directed to a hair dye and processes for using such a hair dye. U.S. '544 at col. 1, line 65 through col. 2, line 22, discloses a composition of (i) at least one monohydroxyindole, and (ii), at least one 5,6-disubstituted hydroxyindole in a medium suitable for dyeing. (emphasis added). U.S. '544 does not disclose compositions that include a pharmaceutically acceptable carrier nor does it disclose any composition useful for pharmaceutical purposes.

The present invention, in contrast, is directed to pharmaceutical compositions and methods of treating diseases with medically effective amounts of a positive modulator of a nicotinic receptor agonist. Particularly, the claims as amended herein are directed to a pharmaceutical composition comprising a positive modulator of a nicotinic receptor agonist wherein said positive modulator is 5-hydroxyindole together with a pharmaceutically acceptable carrier, and to methods for the treatment of a condition associated with reduced nicotine transmission, comprising administering to a patient in need of such treatment, a medically effective amount of a positive modulator of a nicotinic receptor agonist wherein said positive modulator is 5-hydroxyindole.

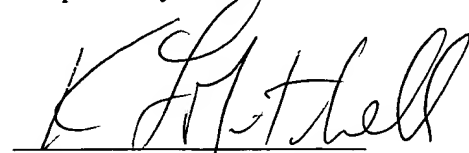
Simply stated, the present invention is not disclosed or taught by Grollier *et al.*, (US Patent 5,135,544. Therefore, Claim 29 being cancelled, Applicant respectfully requests that the Examiner withdraw the rejection of Claim 1 of the present application under 35 U.S.C. S 102(b) as being anticipated.

**Conclusion:**

In view of the arguments and amendments presented herein Applicants respectfully request that the Examiner consider the claims as now presented, and solicit prompt issuance of a Notice of Allowance

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Respectfully submitted



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